

**Introduced by Senator Stone**

January 29, 2015

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An act to add Article 4.1 (commencing with Section 111546) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs and devices.

**LEGISLATIVE COUNSEL'S DIGEST**

SB 149, as introduced, Stone. Investigational drugs, biological products, or devices: right to try.

Existing law, the federal Food, Drug, and Cosmetic Act, prohibits a person from introducing into interstate commerce any new drug unless the drug has been approved by the federal Food and Drug Administration (FDA). Existing law requires the sponsor of a new drug to submit to the FDA an investigational new drug application and to then conduct a series of clinical trials to establish the safety and efficacy of the drug in human populations and submit the results to the FDA in a new drug application.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of drugs and devices and is administered by the State Department of Public Health. A violation of that law is a crime. The Sherman Food, Drug, and Cosmetic Law prohibits, among other things, the sale, delivery, or giving away of a new drug or new device unless either the department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or the drug or device has been approved pursuant to specified provisions of federal law, including the federal Food, Drug, and Cosmetic Act.

The Medical Practice Act provides for the licensure and regulation of physicians and surgeons by the Medical Board of California and

requires the board to take action against a licensee who is charged with unprofessional conduct. The Osteopathic Act provides for the licensure and regulation of osteopathic physicians and surgeons by the Osteopathic Medical Board of California and requires the board to enforce the Medical Practice Act with respect to its licensees.

This bill, among other things, would permit a manufacturer of an investigational drug, biological product, or device to make the product available to eligible patients with terminal illnesses, as specified. The bill would provide that the act does not require a health benefit plan, as defined, or governmental agency to provide coverage for the cost of any investigational drug, biological product, or device made available pursuant to these provisions. The bill would authorize a health benefit plan to provide coverage for an investigational drug, biological product, or device. The bill would also prohibit the Medical Board of California and the Osteopathic Medical Board of California from taking any disciplinary action against the license of a physician based solely on the physician's recommendation to an eligible patient regarding, or prescription for, or treatment with, an investigational drug, biological product, or device.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. Article 4.1 (commencing with Section 111546)  
2 is added to Chapter 6 of Part 5 of Division 104 of the Health and  
3 Safety Code, to read:

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5 Article 4.1. Right to Try Act  
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7 111546. This article shall be known and may be cited as the  
8 Right to Try Act.

9 111546.1. In this article, unless the context otherwise requires,  
10 the following definitions shall apply:

11 (a) "Eligible patient" means a person to whom all of the  
12 following conditions apply:

13 (1) He or she has a terminal illness as determined by that  
14 person's physician and a consulting physician.

15 (2) His or her physician has determined that the person has no  
16 comparable or satisfactory United States Food and Drug

1 Administration approved treatment options available to diagnose,  
2 monitor, or treat the disease or condition involved, and that the  
3 probable risk to the person from the investigational drug, biological  
4 product, or device is not greater than the probable risk from the  
5 disease or condition.

6 (3) He or she has received a prescription or recommendation  
7 from his or her physician for an investigational drug, biological  
8 product, or device.

9 (4) He or she has given written informed consent for the use of  
10 the investigational drug, biological product, or device, or if he or  
11 she is a minor or lacks the capacity to provide informed consent,  
12 his or her parent, legal guardian, or legally authorized  
13 representative has given written informed consent on his or her  
14 behalf.

15 (5) He or she has documentation from his or her physician that  
16 the patient has met the requirements of this subdivision.

17 (b) “Health benefit plan” means any plan or program that  
18 provides, arranges, pays for, or reimburses the cost of health  
19 benefits. “Health benefit plan” includes, but is not limited to, a  
20 health care service plan contract issued by a health care service  
21 plan, as defined in Section 1345 of this code, and a policy of health  
22 insurance, as defined in Section 106 of the Insurance Code, issued  
23 by a health insurer.

24 (c) “Health facility” has the same meaning as in Section 1250.

25 (d) “Investigational drug, biological product, or device” means  
26 a drug, biological product, or device that has successfully  
27 completed phase one of a clinical trial approved by the United  
28 States Food and Drug Administration, but has not been approved  
29 for general use by the United States Food and Drug Administration  
30 and remains under investigation in a clinical trial approved by the  
31 United States Food and Drug Administration.

32 (e) “Physician” means a physician and surgeon licensed under  
33 the Medical Practice Act or an osteopathic physician and surgeon  
34 licensed under the Osteopathic Act, and who is providing medical  
35 care or treatment to the eligible patient for the terminal illness, but  
36 does not include a primary care physician.

37 (f) “State regulatory board” means the California Medical Board  
38 or the Osteopathic Medical Board of California.

39 (g) “Terminal illness” means a disease that, without  
40 life-sustaining procedures, will result in death in the near future

1 or a state of permanent unconsciousness from which recovery is  
2 unlikely.

3 111546.2. (a) Notwithstanding Section 110280, 111520, or  
4 111550, a manufacturer of an investigational drug, biological  
5 product, or device may make available the manufacturer's  
6 investigational drug, biological product, or device to an eligible  
7 patient pursuant to this article. This article does not require that a  
8 manufacturer make available an investigational drug, biological  
9 product, or device to an eligible patient.

10 (b) A manufacturer may do any of the following:

11 (1) Provide an investigational drug, biological product, or device  
12 to an eligible patient without receiving compensation.

13 (2) Require an eligible patient to pay the costs of or associated  
14 with the manufacture of the investigational drug, biological  
15 product, or device.

16 (3) Require an eligible patient to participate in data collection  
17 relating to the use of the investigational drug, biological product,  
18 or device.

19 (c) (1) Except as otherwise required by law, this article does  
20 not require a health benefit plan or any state agency to provide  
21 coverage for the cost of any investigational drug, biological  
22 product, or device.

23 (2) A health benefit plan may provide coverage for an  
24 investigational drug, biological product, or device.

25 111546.3. (a) Notwithstanding any other law, a state regulatory  
26 board shall not revoke, fail to renew, or take any other disciplinary  
27 action against a physician's license based solely on the physician's  
28 recommendation to an eligible patient regarding, or prescription  
29 for, or treatment with, an investigational drug, biological product,  
30 or device pursuant to this article.

31 (b) Notwithstanding any other law, a state agency shall not take  
32 any action against a health facility's license based solely on the  
33 facility's participation in the treatment by or use of an  
34 investigational drug, biological product, or device pursuant to this  
35 article.

36 (c) A violation of this article shall not be subject to Chapter 8  
37 (commencing with Section 111825).

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